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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/767,578	01/23/2001	Ilya Trakht	55099-B/JPW/KRD	2749

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EXAMINER

SCHWADRON, RONALD B

ART UNIT PAPER NUMBER

1644

DATE MAILED: 03/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/767,578

**Applicant(s)**

TRAKHT, ILYA

**Examiner**

Ron Schwadron, Ph.D.

**Art Unit**

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 29-34 and 74 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 29-33 is/are rejected.
- 7) ☒ Claim(s) 34, 74 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

1. Claims 29-34,74 are under consideration.
2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 29-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support in the specification as originally filed for the recitation of "human antibody nonproducing myeloma cell" or "mouse antibody nonproducing myeloma cell" in claim 29 or 30. Regarding applicants comments about the specification, page 29, the cited passages of the specification are drawn to use of specific myeloma cell lines to produce *B6B11 or B6B11-like cells* (B6B11 cells were made from a fusion of HAT-sensitive and G-418 resistant myeloma X63.Ag8.653 cells and subclone of human myeloma RPMI 8226 selected for non secretion of lambda light chains). The aforementioned passages do not disclose the production of other heteromyeloma cell lines and therefore the disclosure is not of the scope of the instant limitation which encompasses use of any myeloma cell lines to produce heteromyeloma cells other than B6B11 or B6B11 like cells. The cited passages of the specification, page 37-38 disclose experimental procedures used to produce the B6B11 cell line. The specification page 35 similarly refers to B6B11 hybrid cells.

There is no support in the specification as originally filed for the scope of the claimed invention (aka the claimed invention constitutes new matter).

Regarding applicants comments about the specification, pages 12-13, said pages do not disclose the limitation under consideration. Regarding applicants comments about the specification, page 29, the cited passages of the specification are drawn to use of specified myeloma cell lines to produce *B6B11 or B6B11-like cells* (B6B11 cells were made from a fusion of HAT-sensitive and G-418 resistant myeloma X63.Ag8.653

cells and subclone of human myeloma RPMI 8226 selected for non secretion of lambda light chains). The aforementioned passages do not disclose the production of other heteromyeloma cell lines and therefore the disclosure is not of the scope of the instant limitation which encompasses use of any myeloma cell lines to produce heteromyeloma cells other than B6B11 or B6B11 like cells. RPMI 8226 and x63.Ag8.653 are specific cell lines with specific properties that are not of the scope of the claimed invention which reads on any cell with the limitation under consideration. In addition, the specification, page 42, lines 26-31 discloses that B6B11 (and therefore the cells used to make said heteromyeloma) has the property that it "can be used to make human hybridomas by fusing with human lymph node-derived lymphocytes or spleen derived lymphocytes, B6B11 was not capable of fusing with human peripheral blood lymphocytes (PBL) or resulted in a very low yield of hybrids". Thus, B6B11 (and the cells used to make said heteromyeloma) have specific subset of properties not disclosed in the claim wherein the claim encompasses cells which do not have the aforementioned property. The mouse myeloma cell used and B6B11 as per the specification, page 42 are both resistant to G-418 and 8-Ag wherein the cells recited in the claim do not necessarily have this feature. Regarding applicants comments about page 9 and page 28 of the specification, neither of said passages disclose the limitation under consideration. The written description provided in the specification is not commensurate with the scope of the claimed invention (e.g. the claimed invention constitutes new matter). Applicant appears to be arguing that the terms under consideration are obvious in view of a specific example disclosed in the specification, even though the specific example does not provide written description of the scope of the claimed invention. However, obviousness is not the appropriate standard with regards to issues of written description. The CAFC stated in Lockwood v. American Airlines Inc., 41 USPQ2d 1961 (Fed. Cir. 1997) that:

***3. Patentability/Validity -- Specification -- Written description (' 115.1103)***

*Patent's entitlement to earlier filing date extends only to that which is disclosed in prior application, and does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed; one shows that one is "in possession" of invention of patent by describing invention, with all its claimed limitations, not that which*

*makes it obvious, and although prior application need not describe claimed subject matter in exactly same terms used in claims, prior specification must contain equivalent description of claimed subject matter, and description which renders obvious invention for which earlier filing date is sought is not sufficient.*

The CAFC also stated in *Lockwood v. American Airlines Inc.*, 41 USPQ2d 1961 (Fed. Cir. 1977) that:

The invention is, for purposes of the 'written description' inquiry, whatever is now claimed .") (emphasis in original). One does that by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention. Although the exact terms need not be used in haec verba , see *Eiselstein v. Frank* , 52 F.3d 1035, 1038, 34 USPQ2d 1467, 1470 (Fed. Cir. 1995) (" [T]he prior application need not describe the claimed subject matter in exactly the same terms as used in the claims.. . ."), the specification must contain an equivalent description of the claimed subject matter. A description which renders obvious the invention for which an earlier filing date is sought is not sufficient.

4. Claims 34 and 74 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached Monday to Thursday from 7:30am to 6:00pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at 571 272 0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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